UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/438,358	11/12/99	GERARD G	0942.4640001

HM22/0620

STERNE KESSLER GOLDSTEIN & FOX PLLC
SUITE 600
1100 NEW YORK AVENUE NW
WASHINGTON DC 20005-3934

EXAMINER	
LEFFERS JR, G	
ART UNIT	**PAPER NUMBER**
1636	4

DATE MAILED: 06/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

U.S. G.P.O. 1999 460-693

Office Action Summary	Application No. 09/438,358	Applicant(s) Gerard, et al.
	Examiner Gerald G. Leffers Jr.	Group Art Unit 1636

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-64* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-64* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application/Control Number: 09/438,358

Art Unit: 1636

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 55-64, drawn to compositions for use in recombinational cloning methods comprising at least one ribosomal protein and at least one recombination protein, classified in class 435, subclass 183; class 536, subclass 23.1.

II. Claims 14-30, only as drawn to in vivo methods for recombinational cloning, classified in class 435, subclasses 91.4, 455, 468 and 478.

III. Claims 14-51, only as drawn to in vitro methods for recombinational cloning, classified in class 435, subclass 91.4.

IV. Claims 52-54 drawn to recombinant nucleic acids and transformed host cells, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Groups II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case, the compositions of Group I can be used in the methods of Group II or Group III.

Inventions of Group I and Group IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the invention of Group IV has separate utility such as use in conventional cloning methods for generation of vectors comprising desirable qualities (e.g. insertion of a desired coding sequence at a particular restriction site within the product of Group IV). The invention of Group IV can be used with recombination substrates which have been produced by a combination of conventional synthesis and recombinant DNA methods. See MPEP § 806.05(d).

Inventions of Groups II and III are biologically and functional different and distinct from each other and thus one does not render the other obvious. The methods of Groups II and III comprise steps which are not required for or present in the methods of the other groups: expression of an effective amount of a recombinase within transformed cells from suitable expression constructs (Group I) and forming a mixture in vitro of an effective amount of a recombinase protein, DNA substrates and ribosomal proteins (Group II). The end results of the different methods are different: generation of recombination products within a cellular milieu (Group I) which will reasonably be expected to be different in composition and require different modes of recovery and analysis than the recombination products produced in vitro (Group II). Thus, the operation, function and effects of these different methods are different and distinct

from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups II-III and Group IV are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of Group IV can be obtained by the processes of Group II or Group III, or by a combination of conventional synthesis and recombinant DNA methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the non-patent literature search for each of Groups II and III are not required for the other group (e.g. construction and use of suitable expression vectors for expression of recombination and ribosomal proteins in vivo (Group I) and in vitro recombination reactions (Group II)), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I Species I (types of ribosomal proteins), please pick one of claims 6, 7, 8 and 9. If claim 6 is chosen, please also pick one member of the Markush group of claim 6. Group I Species II (types of ribosomal proteins), please pick one of claims 58, 59, 60 and 61, and make it

consistent with the claim chosen from Group I Species I. If claim 58 is chosen, please pick a member of the Markush group from within claim 58.

Group II Species I (types of ribosomal proteins), please pick one of claims 24, 25, 26 and 27. If claim 24 is chosen, please pick one member of the Markush group of claim 24.

Group III Species I (types of ribosomal proteins), please pick one of claims 24, 25, 26 and 27. If claim 24 is chosen, please pick one member of the Markush group of claim 24. Group III Species II (types of ribosomal proteins), please pick one of claims 45, 46, 47 and 48, and make it consistent with the claim chosen from Group III Species I. If claim 45 is chosen, please pick one member of the Markush group of claim 45. Group III Species III (vector types), from claim 36 please pick either prokaryotic or eukaryotic vectors. If eukaryotic vectors are chosen, then please pick a member of the Markush group of claim 37. If prokaryotic vectors are chosen, please pick a member of the Markush group of claim 38.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the following claims are generic for each Group/Species combination: Group I Species I-claims 1, 3 and 6 are generic. Group I Species II-claims 55 and 57-58 are generic. Group II Species I-claims 14, 21 and 24 are generic. Group III Species I-claims 14, 21 and 24 are generic. Group III Species III-claims 40, 42 and 45 are generic. Group III Species III-claims 36-38 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Brian Del Buono on or about 5/11/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GLJ

G. Leffers, Jr.

Patent Examiner

Art Unit 1636

June 16, 2000

TERRY MCKELVEY
PRIMARY EXAMINER